UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

April 25, 2017

OPP Decision Number: 523712

Subject: **PRIA 3 Determination to Not Grant Letter**
Product Name: SPOREX
EPA File Symbol: 87518-A
Application Date: 28 October 2016
EPA Receipt Date: 31 October 2016

Henry Dao
President/CEO
HSP USA, LLC
3111 Route 38, Suite 11, #310
Mount Laurel, NJ 08054

Dear Mr. Dao:

Our records indicate that the decision review period for EPA to make a determination pursuant to section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA), as amended, regarding the above referenced application ends on April 25, 2017. The Agency has reviewed the application. On March 10, 2017, the Agency emailed to you a 75-Day letter and informed you that the application was inadequate and described the deficiencies that needed to be addressed. The Agency provided you with some additional information on April 10th and 12th in response to some questions you posed after receiving the 75-Day letter. The Agency's decision to make this determination is based on the following chronology, including correspondence with you and efforts undertaken to resolve the issues. This chronology also incorporates actions and past discussions for EPA File Symbol 87518-U (Product Name Hsp_2O SPX), which was withdrawn on September 7, 2016. This withdrawn application is an important part of this chronology because in correspondence with you about your current application, File Symbol 87518-A (Product Name SPOREX), there have been references to what was done previously in support of the withdrawn application for Hsp_2O SPX:

- October 19, 2015 – The Agency received the application for Hsp_2O SPX, EPA File Symbol 87518-U. Based on the submitted test data, including the Confidential Statement of Formula (CSF), the active ingredient in the proposed product was hypochlorous acid.

- January 14, 2016 – The Agency sent to you, by email, a copy of the technical screen failure based on the efficacy review. Based on that review, EPA stated that you needed to provide test data on organisms to support the hospital disinfection claims (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) and data to support fungicide claims (*Trichophyton mentagrophytes*). Later that day, you alerted EPA that the data submitted for Hsp_2O SPX was cited from another proposed product that you had submitted and was currently undergoing review (Hsp_2O) Pro [87518-G]) and a currently registered product (EPA Registration No. 87518-1 [Hsp_2O]).

- January 15, 2016 – The Agency responded, by email, that the cited data for File Symbol 87518-G and EPA Registration No. 87518-1 could not be used to support the registration for your proposed product. The reason was that those two products have different pH ranges which may affect the efficacy. Later that day, you asked, by email, what data would be needed to address the deficiency. EPA responded to your email, by email, later that day by stating that (and again, as identified in the Technical Screen) test data must be tested on the appropriate organisms for hospital disinfection (*Pseudomonas aeruginosa* and *Staphylococcus aureus*). Later that day, you sent an email asking whether confirmatory testing would be sufficient to support the current submitted data. EPA responded later that day, by email, to your inquiry and explained that a full study would be needed to support the hospital disinfection claims. Confirmatory testing on the organism, *Trichophyton mentagrophytes,* would be needed to support fungicide claims. You responded later that day, by email, that you would be able to provide these data to EPA in a short time frame.

- February 3, 2016 – The Agency contacted you by phone, reiterating what efficacy data would be needed to support the Hsp_2O SPX. EPA also mentioned that a potential time extension would be needed. However, the Agency was waiting for the final acute toxicity and product chemistry reviews to be completed to determine if there were any other deficiencies that needed to be addressed. You contacted EPA, later that day by email, providing a status of the data you were generating to support the deficiencies.

- February 12, 2016 – The Agency received study reports for *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Those data were put into science review.

- March 14, 2016 – The Agency received a study report for *Trichophyton mentagrophytes.* Those data were put into science review.

- April 7, 2016 – The Agency emailed to you a 75-day letter informing you that the application was incomplete due to acute toxicity, efficacy, and product chemistry data deficiencies. The deficiencies were identified and discussed in attachments which accompanied the letter.

- April 8, 2016 – You sent to the Agency, a letter, requesting a 5-month time extension for Hsp_2O SPX. The new PRIA timeframe for this application would then be September 11, 2016.

- April 19, 2016 – The Agency received a bridging argument to support acute toxicity deficiencies. The bridging argument was put into science review.

- May 9, 2016 – The Agency received study reports for product chemistry. Those data were put into science review.

- September 2, 2016 – The Agency emailed to you a 75-Day letter alerting you that the application was incomplete due to acute toxicity, efficacy, and product chemistry data deficiencies. The deficiencies were identified and discussed in attachments which accompanied the letter. Upon review of the formulation, it was determined that the active ingredient for the product was sodium hypochlorite and not hypochlorous acid. As a result, the acute toxicity, efficacy, and product chemistry data submitted in support of the application were not acceptable.

- September 7, 2016 – The Agency had a conference call with you regarding the deficiencies with your application. At that time, it was recommended that you withdraw the application. At that time, you were informed that if you chose to submit any future submissions, the application would require supporting studies for the appropriate active ingredient (sodium hypochlorite). You were earlier informed by the 75-Day letter (dated September 2, 2016) and attachments that your product contained sodium hypochlorite and not hypochlorous acid. EPA determined this finding based upon the pH data submitted by you. After the meeting, you submitted a request to withdraw the application by email dated September 7, 2016.

- October 28, 2016 – You submitted a new product application (Product Name SPOREX, EPA File Symbol 87518-A). This application was a resubmission of the (Hsp_2O) SPX product application that was withdrawn in September, 2016. Product information, which included acute toxicity, efficacy and product chemistry data, were submitted to support the application. The data submitted were the same information as previously submitted to support (Hsp_2O) SPX. Specifically, the active ingredient in the resubmitted data was hypochlorous acid – again – not the active ingredient in your product.

- December 13, 2016 – The Agency began review of the acute toxicity, efficacy, and product chemistry data for your application.

- January 9, 2017 – The Agency emailed to you a 10-Day Deficiency Letter that outlined acute toxicity, efficacy, and product chemistry data deficiencies. As part of that letter, you received the 45-Day technical screens for acute toxicity, efficacy, and product chemistry outlining for each discipline how your data were not adequate. Based on your email response, you received that email on January 9, 2017.

- January 11, and 12, 2017 – On both days, you contacted the Agency by email to get clarifications about how the acute toxicity and product chemistry deficiencies could be addressed. EPA provided you with guidance about how to deal with the issues for those two disciplines.

- January 16, 2017 – You sent an email response to the 10-Day Deficiency letter attempting to address the acute toxicity, efficacy, and product chemistry concerns. But still, hypochlorous acid was the tested substance and not the correct active ingredient.

- March 10, 2017 – The Agency emailed to you a 75-Day letter informing you that the application was incomplete due to acute toxicity, efficacy, and product chemistry data deficiencies. The deficiencies were outlined in the attached Data Evaluation Records that were a part of that email. Among other things, that email informed you, once again, that your data failed to address the correct active ingredient. Your data addressed hypochlorous acid which is not the active ingredient in your product. You received EPA's email on March 10, 2017. On that same day, you emailed the Agency and discussed your actions to date.

- March 21, 2017 – The Agency had a conference call with you regarding the deficiencies outlined in the 75-Day letter and the options available to you for addressing those issues under the PRIA deadline for this application. You inquired if setting a new PRIA deadline would be an option moving forward with the application. Based on the extent of the deficiencies, it was communicated that extending the PRIA timeframe would not be a possibility. You stated that you would like to confirm this position with the Regulatory Branch Chief, Rose Kyprianou. Later that day, you communicated with Ms. Kyprianou, via email, and stated that you followed Agency guidance in addressing the deficiencies with the application. Ms. Kyprianou alerted you that Product Manager (Demson Fuller) would be setting up a meeting to discuss your deficiencies in further detail.

- March 23, 2017 – The Agency had a conference call with you regarding the deficiencies with the application with the Regulatory Branch Chief participating, and you were informed that extending the PRIA timeframe would not be an option. EPA determined that the deficiencies are identical to the issues associated with the Hsp_2O SPX application. It was explained during the call that EPA has attempted to work with you in the past in submitting test data to support the SPOREX application. Based on the test data submitted for the SPOREX application, you still failed to address the appropriate active ingredient, which was explained to you as being the same issue with the withdrawn Hsp_2O application. Based on the extent of the deficiencies (i.e., all new test data needed to be submitted for acute toxicity, efficacy, and product chemistry), EPA determined it would not grant a time extension for your SPOREX application. You were also informed that you could withdraw the application. If you chose not to withdraw, EPA would move forward with a Do Not Grant letter. You stated that you were still unclear as to how to address the deficiencies. You requested a meeting to discuss your concerns further with the science staff. You stated that, after the discussion with the science staff, you would let the Agency know your chosen option to address the deficiencies with the application. Later that day, you also communicated back to EPA, via email, that you would address all the deficiencies within two weeks. Also in that email, you requested an extension to the current PRIA timeframe.

- March 28, 2017 – The Agency sent you an email alerting you that a meeting would be set up with the science staff to discuss your concerns. In preparation for this discussion, EPA asked that you provide an agenda or questions in advance of the discussion. You responded, on that day, by stating that you would provide a recap as to what was previously discussed in past meetings with the Agency and possibly provide questions that you would like addressed if needed.

- March 29, 2017 – You sent to the Agency, by email, a recap of certain interactions with the EPA since October 2015, which included discussions regarding Hsp_2O SPX.

- March 30, 2017 – The Agency had a conference call with you regarding the deficiencies with the application. Science staff were present for this discussion. EPA informed you what test data were needed to support your application. To date, the test data you have submitted to support this application still reflects hypochlorous acid as the active ingredient. All of the product chemistry data submitted to support your proposed product were conducted on Hsp_2O SPX, and "Hsp_2O SPX" is listed as such in the study titles for MRID Nos. 49917601, 49917602 and 49917603. Therefore, those data developed on hypochlorous acid are not acceptable to support that discipline. For efficacy, the active ingredient measured in the test substance in the cited studies was hypochlorous acid. Since the active ingredient in your proposed product is sodium hypochlorite, those data are not acceptable for that discipline. Lastly, since the CSF is not acceptable, the Agency cannot determine if this product is substantially similar to the product you referenced in your application. During the conference call, it was explained to you that any new test data to support this submission must be for the active ingredient that you are supporting in your product (sodium hypochlorite). You were informed that if you wanted to rely on existing data to support this submission, you would need to submit documentation (raw data, study reports) to substantiate your claim that the test substance was sodium hypochlorite. During the conference call discussion, you stated that you did not intend to withdraw and would provide test data to support your application by the deadline date in the 75-Day letter, which is May 24, 2017. You also asked, alternatively, if a time extension would be a possibility in allowing you the opportunity to provide additional information to address the deficiencies. Again, it was explained to you that a PRIA time extension would not be an option in support of this application as discussed in the March 23, 2017 conference call. It was also explained that if you intended to not to withdraw the application and to provide the test data by May 24, 2017, this was acceptable because you will have responded to the 75-Day letter within the appropriate timeframe (75-Day period ends on May 24, 2017). However, it was further explained to you that the Agency will move forward in meeting its obligations under the current PRIA timeframe and will issue a Do Not Grant for your application. EPA will continue to work on the application if you submit the new test data before the expiration of the 75-Day period.

- March 31, 2017 – You sent to the Agency, by email, a summary of the meeting on March 30, 2017. You requested EPA to confirm if you needed to incorporate lab memos on antibiotic resistance and acid resistance data for future submissions. In

addition, you requested confirmation as to whether you could test the most difficult to kill virus (Norovirus) to bridge viral data.

- April 10, 2017 – The Agency sent you, by email, a response to your summary of the March 30, 2017 meeting. Specifically, EPA alerted you again, that all test data must be submitted on sodium hypochlorite, not hypochlorous acid.

- April 12, 2017 – The Agency sent you an email to address the specific efficacy questions you wanted confirmed that were not provided to you in the April 10, 2017 email from EPA.

The Agency, in meeting its obligation to make a determination within the PRIA decision review period, has determined that your application does not meet the standard for registration under FIFRA and, therefore, cannot be granted at this time.

The application's deficiencies are included in the attached 75-Day deficiency notice. Additionally, as noted earlier, the Agency provided you with some additional information on April 10, and 12, 2017 in response to some questions you posed after receiving the 75-Day deficiency notice.

Although this concludes EPA's PRIA review of your application, this determination is not a denial of your application pursuant to section 3(c)(6) of FIFRA. A 75-Day deficiency letter has been issued on March 10, 2017 prior to this letter. Pursuant to 40 CFR § 152.105, you have 75 days from the March 10, 2017 letter to address the deficiencies or notify the Agency when the information will be submitted to address the deficiencies. You have the following four options.

1. **Resolve the issue(s)**. You may resolve the issue(s) identified in the 75-Day deficiency letter dated March 10, 2017 by submitting the required information/data/studies by May 24, 2017, or by submitting an explanation of why it will take longer to correct the deficiency or deficiencies, including your written commitment and schedule to respond to the deficiencies. The Agency will then continue to diligently work with you in resolving the deficiencies without a PRIA decision due date.

2. **Do nothing**. If you do not respond to this letter, the Agency will administratively withdraw your application on May 24, 2017. Since a fee was paid, the Agency will provide any applicable refund as soon as practicable. Once the application is withdrawn, if you decide to pursue this action again, you will need to submit a new application, including either the appropriate fee or 25% or 50% of the fee and a request for a waiver of the remainder of the fee.

3. **Withdraw the application**. You may withdraw your application. Since a fee was paid, the Agency will provide any applicable refund as soon as practicable. Once the application is withdrawn, if you decide to pursue this action again, you will need to submit a new application, including either the appropriate fee or 25% or 50% of the fee and a request for a waiver of the remainder of the fee.

4. **Request a denial**. Because this determination is not a denial under section 3(c)(6) of FIFRA, you may request that EPA issue such a denial by responding to the Agency prior to May 24, 2017. The Agency may then initiate a denial process, based upon the record before the Agency as of the date of this letter, as described in section 3(c)(6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

If you have questions concerning this letter, please contact Product Manager Demson Fuller by telephone (703) 308-8062 or by e-mail at fuller.demson@epa.gov, or Regulatory Action Leader Srinivas Gowda by telephone at (703) 308-6354 or by e-mail at gowda.srinivas@epa.gov.

Sincerely,

Richard P. Keigwin, Jr., Acting Director
Office of Pesticide Programs, (7510P)